REMARKS

Claims 50-96 are currently pending. Reconsideration is respectfully requested based on the claim amendments and traversals discussed below. No new matter has been added.

I. Claim Objections

Claims 54 and 55 have been objected to because claim 54 depends from cancelled claim 2. Applicants have amended claim 54 to depend from claim 51.

Claims 62 and 75 have been objected to for reciting the term "plane." Applicants have amended claims 62 and 75 to recite the term "planar" in place of the term "plane."

Applicants respectfully request that the objections to claims 54, 55, 62 and 75 be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 103

Claims 50-57, 59, 65-68, 72-85 and 93-96 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Funderburk et al. (U.S. Patent No. 6,093,172) in view of Turner et al. (U.S. Patent No. 4,817,603). As acknowledged by the Examiner, Funderburk does not disclose a cover over the forward end of the housing.

Applicants respectfully traverse the Examiner's rejection based on Funderburk in view of Turner since the references alone or in combination fail to teach or suggest a sterile insertion set, a device housing wherein the insertion set is within the device housing, a plunger, a spring and a releasable cover member covering the forward end wherein the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

Funderburk discloses an automatic injector 10 that is particularly designed for placement of the insertion needle 12 of a subcutaneous insertion set 14. (Col. 4, line 66-Col. 5, line 2.) The insertion set 14 is provided as a separate assembly for insertion into the plunger of the injector by the user. See FIGS. 30 and 31 demonstrating insertion of the insertion set 14 into the injector 210. As described in the specification, "An enlarged base, typically in the form of resilient or flexible wings 24, is provided on the housing 20 [of the insertion set 14] for stable affixation to the skin of the patient." (Col. 5, lines 23-25.) "The

nose end of the barrel 28 defines an opposed pair of relatively wide and opened-ended cutouts 40 for slide-fit reception of the oppositely projecting base wings 24 [of the insertion set 14]." (Col. 6, lines 3-6.) The wings 24 of the insertion set 14 are shown extending radially outwardly through the cutouts 40, 140 and beyond the barrel of the injector device in FIGS. 1, 17, 30, 31 and 33. Funderburk fails to teach or suggest an insertion set within the device housing. As acknowledged by the Examiner, Funderburk also fails to teach or suggest a releasable cover member covering the forward end. In addition, Funderburk fails to teach or suggest that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member.

Turner discloses a lancet device for performing a pricking operation. (Abstract.) Turner discloses a device including a closed end with an aperture through which a needle passes to prick the finger of the user. The Turner device does not teach or suggest an insertion set with a housing and a hollow cannula provided with the lancet device. Further, the Turner device is not configured for reception of an insertion set within the device housing or for delivery of an insertion set. The opening in the finger guard plate is sized only for a lancet to pass through.

In each of the embodiments shown, an outlet aperture is provided in a finger guard plate in the housing through which a needle is driven. For example, FIG. 1, shows a finger guard plate 26 having a central aperture 28 through which the needle moves to prick the user's finger. (Col. 4, lines 47-49.) In operation, the needle assembly is released and driven by the spring up into contact with the end plate 26 and the needle 34 pricks the finger through the hole 28. (Col 6, lines 8-12.) The Turner device is designed for puncturing the skin through a small opening in the finger guard plate. Turner does not teach or suggest a device that can deliver an insertion set to the skin. Turner also does not teach or suggest a bore upstanding from the cover member.

In contrast, Applicants' claimed invention in independent claims 50 and 72 requires an insertion set within the device housing wherein the cover member covering the forward end and the housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Applicants' claimed invention in claim 93 requires a releasable cover member covering a forward end of the housing and that the cover

member include an upstanding portion defining a bore. As discussed above and acknowledged by the Examiner, Funderburk does not disclose a cover. Funderburk also fails to teach or suggest an insertion set within the device housing and that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Turner does not make up the deficiencies of Funderburk and also fails to teach or suggest an insertion set within the device housing and that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Turner further fails to teach or suggest that the cover member includes an upstanding portion defining a bore. Together or individually, Funderburk and Turner fail to teach or suggest the claimed invention in claims 50, 72 and 93 and the claims dependent thereon.

Therefore, Applicants respectfully request that the rejection of claims 50-57, 59, 65-68, 72-85 and 93-96 under 35 U.S.C. §103(a) be withdrawn.

Claims 50-59, 65-88 and 90-92 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Funderburk et al. (U.S. Patent No. 6,093,172) in view of Karakashian (U.S. Patent No. 3,937,219).

Applicants respectfully traverse the Examiner's rejection based on Funderburk in view of Karakashian since the references alone or in combination fail to teach or suggest a sterile insertion set, a device housing wherein the insertion set is within the device housing, a plunger, a spring and a releasable cover member covering the forward end wherein the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142. Funderburk has been discussed above and fails to teach or suggest an insertion set within the device housing. As acknowledged by the Examiner, Funderburk also fails to teach or suggest a releasable cover member covering the forward end. In addition, Funderburk fails to teach or suggest that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member.

Karakashian discloses a sterile syringe assembly for providing sterile air to be injected into a patient. (Abstract.) Syringe 4 is mounted on syringe platform 2. Both the syringe 4 and the syringe platform 2 are mounted within enclosure package 8 with the plunger 5 at least partially pulled back to provide a predetermined volume of sterilized air within an internal chamber. (*See* Col. 2, lines 13-22.) In operation, enclosure package 8 is sealed throughout a peripheral boundary of the enclosure contour. The assembly 1 is then sterilized. (*See* Col. 3, lines 19-26.) Karakashian discloses a syringe packaged within a gas sterilizing enclosure where the packaging surrounds the platform on which the syringe is mounted and the enclosure is sealed at its edges. Karakashian fails to teach or suggest an insertion set within a device housing. Karakashian also fails to teach or suggest a releasable cover member covering the forward end of the of the devise housing wherein the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Karakashian fails to make up the deficiencies of Funderburk.

In contrast, Applicants' claimed invention in independent claims 50 and 72 requires an insertion set within the device housing wherein the cover member covering the forward end and the housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Applicants' claimed invention in claim 90 requires providing an injector device housing, placing an insertion set within the injector device housing and applying at least one releasable cover member over at least a portion of the injector device housing to seal the injector device housing. As discussed above and acknowledged by the Examiner, Funderburk does not disclose a cover. Funderburk also fails to teach or suggest an insertion set within the device housing and that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Karakashian does not make up the deficiencies of Funderburk and also fails to teach or suggest an insertion set within the device housing. Karakashian fails to teach or suggest that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. Together or individually, Funderburk and Karakashian fail to teach or suggest the claimed invention in claims 50, 72 and 90 and the claims dependent thereon.

Therefore, Applicants respectfully request that the rejection of claims 50-59, 65-88 and 90-92 under 35 U.S.C. §103(a) be withdrawn.

III. Allowable Subject Matter

Applicants kindly thank the Examiner for indicating that claims 60-64 would be allowable if rewritten in independent form. Applicants have rewritten claim 60 in independent form including all of the limitations in the base claim.

IV. SUMMARY

It is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

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Date

Heidi A. Dare (Reg. No. 50,775)

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200